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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO:	CONFIRMATION NO.
09/456,693	12/09/1999	DASA LIPOVSEK	50036/021002	6778

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/23/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/456,693

Applicant(s)

LIPOVSEK, DASA

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 8-52 is/are pending in the application.
- 4a) Of the above claim(s) 13-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1639

**DETAILED ACTION**

***Election/Restrictions***

Applicant affirms the election with traverse of Group I, claims 1 and 8-12 and reserves the right to pursue all canceled subject matter in this or any currently pending in the future

***Status of Claims***

Claims 1 and 8-52 are pending in the application.

Claims 2-7 have been cancelled in the Amendment of 2/1/02.

Claims 13-52 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1 and 8-12 are under examination.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 8-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility for reasons set forth in the last Office action.

***Response to Arguments***

Applicants argue that the specific asserted utility of the present libraries is described at page 3, lines 11-13. It states

Art Unit: 1639

that the antibody mimics may be utilized for the purpose of designing proteins, which are capable of binding to virtually any compound of interest. Applicants further argued that the specification describes fibronectin-based scaffolds and their use for identifying, selecting and evolving novel binding proteins as well as their target ligands. Applicants rely on WO 02/032925, which evidences that, a fibronectin -scaffold-based library in fact, contain useful TNF-alpha binding proteins. Applicants argue that a library is generally useful for screening for protein-protein interaction and cannot be limited to one specific screen for one specific product.

In reply, the claims do not recite for an antibody mimics. Rather, only a library of proteins derived from the 10<sup>th</sup> module of human fibronectin type III domain. Nor does the specification recite the compounds that have been isolated from the library that binds to TNF-alpha binding proteins. While the compound isolated from the library obviously has the asserted utility, the library, per se, does not have a utility, except, to screen a specific compound that has the specific utility. This is analogous to saying that nature (a collection of compounds), which has been the source for isolating specific compounds, is patentable because compounds isolated therefrom have been found to have a specific utility. To date this has not been the case.

Art Unit: 1639

While the isolated compounds have been patented, nature (collection of compounds) has not been patented.

The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility....A patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . In *Brenner*, the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible compounds the utility of which has also not been identified. *Brenner*, 148 USPQ at 690. (Emphasis ours).

Art Unit: 1639

Claims 1 and 8-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The response above is incorporated herein since applicants incorporated the same arguments above.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action.

Art Unit: 1639

***Response to Arguments***

Applicants argue that the lack of adequate written description for the criteria by which an amino acid is defined applies only to claim 10 and not to claims 1, 8-9 and 11-12. Applicants argue that it is well known in the art as to which amino acid is defined as basic, neutral or acidic by grouping them into three categories of polar, hydrophilic; nonpolar, hydrophobic amino acid and "special" amino acids. There are four highly ionized amino acids which include Glutamic acid (glutamate). Applicants state that the nonpolar, hydrophobic amino acids have side chains that are hydrophobic and are located in the interior of proteins. Applicants present the Molecular Cell Biology textbook for said definitions. But fail to provide a copy of said document. Applicants recite that the R group for ser has a pK of 13, making it a basic amino acid as evident from the cited pK value in the web site.

In response, claim 10 depends on claim 9 which ultimately depends on claim 1. Furthermore, this is only one of the rejections under this statute. While the grouping of amino acids is based on its R groups however, as apparent from applicants' arguments these are not the only basis by which the amino acids have been grouped in the art. Furthermore, there is nothing in

Art Unit: 1639

the specification or cited prior art that categorize Ser as a basic residue or that the salt form of glu (i.e., glutamate) is acidic. The calculation that is based on its pK value is not described in the specification or the prior art not made of record.

Applicants further argue that with the amendment to the claim reciting a library of proteins the there rejection of "scaffold-based" protein no longer applies.

In reply, this amendment is not supported in the as-filed specification. Since the amendment broadens the originally claimed scaffold-based proteins. The claim as amended claims any type of library of proteins including a whole protein. Rather, than only a domain or fragment thereof (i.e., the scaffold portion as in the as-filed specification). [This is a new ground of rejection].

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point



out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

***Response to Arguments***

A. Applicants argue that with the amendment to the claim of a "scaffold-based protein" the rejection has been obviated. In response, it is not clear as to the proteins **derived** from fibronectin type III domain since, the claim recites it is only a domain, not the whole protein itself.

B. Applicants rely on their arguments above as to this rejection.

In reply, the arguments above categorizing Ser as a basic residue is unclear for reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Koide [2002/0019517 which is the same as

Art Unit: 1639

(U.S. 6,462,189] for the same reasons set forth in the last Office action.

***Response to Arguments***

Applicants admit that paragraphs 0022-0028 of Koide state that one or more of the monobody loop regions sequences of the Fn3 polypeptide vary by deletion, insertion or replacement. The paragraph also lists which amino acids make up the AB, BC, CD, DE, EF and FG loops. But argue that despite this general description of the amino acid sequences that make up the FN3 loops, there is no disclosure in the reference of the Fn3-based proteins with at least three randomized loops. Rather, Koide discloses only monobodies in which one or two loops have been varied and suggest that variation of additional sequences would destabilize the entire protein.

In response, as admitted by applicants at page 2, paragraphs 0023-0028 Koide recites that least 5 of the different recited loops that can be randomized. See further example IV, page 12, which recites at least three randomization of the loops. Thus, Koide, specifically recites the at least three (i.e., five) of the specific loop positions that can be randomized.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

Art Unit: 1639

**ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

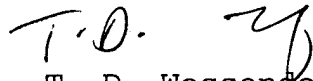
This application contains claims 13-52 drawn to a nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

December 19, 2003